UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION, STATE OF NEW YORK, STATE OF CALIFORNIA, STATE OF OHIO, COMMONWEALTH OF PENNSYLVANIA, STATE OF ILLINOIS, STATE OF NORTH CAROLINA, and COMMONWEALTH OF VIRGINIA, Plaintiffs, -v- VYERA PHARMACEUTICALS, LLC, AND PHOENIXUS AG, MARTIN SHKRELI, individually, as an owner and former director of Phoenixus AG and a former executive of Vyera Pharmaceuticals, LLC, and KEVIN MULLEADY, individually, as an owner and former director of Phoenixus AG and a former executive of Vyera Pharmaceuticals, LLC, Defendants.	20cv706 (DLC) OPINION AND ORDER

APPEARANCES:

For plaintiff Federal Trade Commission:
James H. Weingarten
Markus H. Meier
Amanda Triplett
Armine Black
Bradley S. Albert
Daniel W. Butrymowicz
J. Maren Schmidt
Lauren Peay
Leah Hubinger
Matthew B. Weprin
Neal J. Perlman
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

For plaintiff State of New York:
Amy E. McFarlane
Jeremy R. Kasha
Elinor R. Hoffman
Saami Zain
Office of the New York Attorney General
Antitrust Bureau
28 Liberty Street, 20th Floor
New York, NY 10005

For plaintiff State of California:
Michael D. Battaglia
Office of the Attorney General of California
455 Golden Gate Avenue, Suite 11000
San Francisco, CA 94102

For plaintiff State of Ohio:
Beth Ann Finnerty
Elizebeth M. Maag
Office of the Ohio Attorney General
150 E. Gay Street, 26th Floor
Columbus, OH 43215

For plaintiff Commonwealth of Pennsylvania:
Joseph Betsko
Pennsylvania Office of Attorney General
Strawberry Square, 14th Floor
Harrisburg, PA 17120

For plaintiff State of Illinois:
Richard S. Schultz
Office of the Attorney General of Illinois
100 W. Randolph Street, 11th Floor
Chicago, IL 60601

For plaintiff State of North Carolina:
Jessica V. Sutton
Kip D. Sturgis
North Carolina Dept. of Justice
Consumer Protection Division
114 West Edenton Street
Raleigh, NC 27603

For plaintiff Commonwealth of Virginia:
Sarah Oxenham Allen
Tyler Henry
Office of the Attorney General of Virginia

202 North Ninth Street
Richmond, VA 23219

For defendants Vyera Pharmaceuticals, LLC and Phoenixus AG:
Stacey Anne Mahoney
Sarah E. Hsu Wilbur
Morgan, Lewis & Bockius LLP
101 Park Avenue
New York, NY 10178
(212) 309-6000

Scott A. Stempel
William S. D. Cravens
Melina R. Dimattio
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW
Washington, D.C. 20004

Steven A. Reed
Morgan, Lewis & Bockius LLP
1701 Market Street
Philadelphia, PA 19103
(215) 963-5000

Noah J. Kaufman
Morgan, Lewis & Bockius LLP
One Federal Street
Boston, MA 02210
(617) 341-7700

Michael M. Elliott
Rachel J. Rodriguez
Phillips Nizer LLP
485 Lexington Avenue
New York, NY 10017

Michael L. Weiner
Dechert LLP (NYC)
1095 Avenue of the Americas
New York, NY 10036-6797

For defendant Martin Shkreli:
Christopher H. Casey
Andrew J. Rudowitz
James Manly Parks
Jeffrey S. Pollack
Sarah O'Laughlin Kulik

Duane Morris LLP
30 South 17th Street
Philadelphia, PA 19103

For defendant Kevin Mulleady:
Kenneth R. David
Albert Shemtov Mishaan
Nicholas Anthony Rendino
Kasowitz, Benson, Torres LLP (NYC)
1633 Broadway
New York, NY 10019

DENISE COTE, District Judge:

This Opinion addresses the motions of defendants Vyera Pharmaceuticals, LLC, its parent company Phoenixus AG (together, "Vyera"), Martin Shkreli, and Kevin Mulleady (collectively, "Defendants") to exclude expert testimony to be offered at trial on behalf of plaintiffs the United States Federal Trade Commission ("FTC") and seven States[1] (together, "Plaintiffs") by Professor C. Scott Hemphill. It also addresses the Plaintiffs' motion to exclude certain testimony from the Defendants' expert Dr. Anupam P. Jena, which has been offered in part in rebuttal to the Hemphill testimony. In his trial testimony, which he has submitted by affidavit, Hemphill addresses issues of market power and monopoly power with respect to Vyera's branded drug Daraprim and the existence of anticompetitive effects from the Defendants' conduct. He also calculates Vyera's alleged excess

[1] The seven State plaintiffs are the States of New York, California, Ohio, Illinois, and North Carolina, and the Commonwealths of Pennsylvania and Virginia.

profits. For the following reasons, the Defendants' motion to exclude Hemphill's testimony is denied. The Plaintiffs' motion to exclude Dr. Jena's testimony is granted in part.

Background

The events underlying this action are described in an Opinion of August 18, 2020, which is incorporated by reference. See Fed. Trade Comm'n v. Vyera Pharms., LLC, 479 F. Supp. 3d 31 (S.D.N.Y. 2020) ("Vyera I"). In brief, in August 2015, Vyera acquired the U.S. rights to Daraprim, which is used to treat a potentially fatal infection known as toxoplasmosis, and promptly raised the list price from $17.50 per tablet to $750 per tablet. The first generic equivalent to Daraprim entered the market in March of 2020. The Plaintiffs allege that the Defendants designed and implemented a monopolistic scheme that involved restrictive agreements with distributers and suppliers to block and delay generic drug competition to Daraprim. The Plaintiffs have brought claims for violations of §§ 1 and 2 of the Sherman Act, § 5(a) of the FTC Act, and various state statutes.

A bench trial in this action is scheduled to commence on December 14, 2021. Without objection from the parties, the direct testimony of trial witnesses under the control of the parties was submitted with the Pretrial Order on October 20, 2021. Hemphill's direct testimony is contained in an affidavit

dated October 19; Dr. Jena's direct testimony is contained in an affidavit dated October 20.

On October 20, the parties made various motions in limine and motions to exclude expert testimony.[2] Among those motions, the Defendants moved to exclude three sets of opinions offered by Hemphill. On the same day, the Plaintiffs moved to exclude certain opinions of Dr. Jena, an expert for the Defendants offered to rebut some of Hemphill's testimony. Those motions became fully submitted on November 10.

I. Summary of Hemphill's Testimony

Hemphill is the Moses H. Grossman Professor of Law at New York University and holds a Ph.D. in economics from Stanford University and a M.Sc. in economics from the London School of Economics. His scholarship has focused on the economics of competition in the pharmaceutical industry. He offers his opinions in this case as an economist.

Hemphill analyzed Daraprim pricing and sales data from Vyera's records and data compiled by IQVIA, a commercial healthcare data science company, as well as documents and

[2] Because the motions were submitted on the same day as the direct testimony, the motions describe the experts' reports and anticipate that their direct testimony would be consistent with those reports. The parties' opposition and reply briefs have had the benefit of access to the experts' direct testimony contained in the trial affidavits.

testimony describing Vyera's conduct and the actions of potential generic competitors, in order to opine on Vyera's market power and monopoly power and the effect of Vyera's conduct on generic competition to Daraprim. His opinions rest at least in part on his observations of the change in the average net price of Daraprim before and after Vyera's August 2015 acquisition, the rate of decrease in Daraprim's price upon generic entry into the market in March 2020, changes in quantities of Daraprim sold over time, and indicia of a lack of substitution of other drugs for Daraprim. He concludes that FDA-approved pyrimethamine is the relevant product market and that Vyera had 100% monopoly power over that market from its acquisition of Daraprim until March 2020.

Hemphill also describes and applies a framework to analyze the effect on competition of Vyera's contracts with suppliers and distributors. He concludes that the agreements entered into by Vyera impeded generic entry and met three conditions necessary to harm competition in that market. Finally, Hemphill offers a model for calculating Vyera's excess profits.

II. Summary of Dr. Jena's Testimony

Dr. Jena is the Ruth L. Newhouse Associate Professor of Health Care Policy and Medicine at Harvard Medical School and is an Internal Medicine Specialist in the Department of Medicine at Massachusetts General Hospital. He has been involved in the

care of patients with toxoplasmosis, although he is not an infectious disease specialist. He received a Ph.D. in Economics from the University of Chicago and is a faculty research fellow at the National Bureau of Economic Research.

Dr. Jena's testimony is offered to rebut some of the opinions offered by Hemphill and testimony offered by another expert for the Plaintiffs, Dr. W. David Hardy. Dr. Hardy opines on toxoplasmosis, available treatments, and factors governing the choice of treatment, including the therapeutic substitutability of pharmaceuticals other than FDA-approved pyrimethamine. Daraprim is branded pyrimethamine.

Dr. Jena opines that Hemphill has failed to demonstrate any harm to competition from Vyera's restrictive distribution agreements. He opines as well that Hemphill's conclusions about the relevant market are flawed and that his calculation of Vyera's excess profits rests on faulty assumptions. Dr. Jena also disagrees with Dr. Hardy's opinion that two treatments -- trimethoprim-sulfamethoxazole ("TMP-SMX") and compounded pyrimethamine -- are not readily interchangeable with FDA-approved pyrimethamine.

Discussion

Federal Rule of Evidence 702 governs the admissibility of expert testimony. The proponent of expert testimony carries the burden of establishing its admissibility by a preponderance of

the evidence. United States v. Williams, 506 F.3d 151, 160 (2d Cir. 2007). The trial judge must first address "the threshold question of whether a witness is qualified as an expert by knowledge, skill, experience, training, or education to render his or her opinions." Nimely v. City of New York, 414 F.3d 381, 396 n.11 (2d Cir. 2005) (citation omitted). "To determine whether a witness qualifies as an expert, courts compare the area in which the witness has superior knowledge, education, experience, or skill with the subject matter of the proffered testimony." United States v. Tin Yat Chin, 371 F.3d 31, 40 (2d Cir. 2004).

Even when an expert is qualified, it is the role of a district court to perform a "gatekeeping function" by ensuring that "an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." In re Mirena IUS Levonorgestrel-Related Prod. Liab. Litig. (No. II), 982 F.3d 113, 122–23 (2d Cir. 2020) (quoting Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 597 (1993)). An expert's opinion is relevant if it will "help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702; see Daubert, 509 U.S. at 591. "Expert testimony that usurps the role of the factfinder or that serves principally to advance legal arguments should be excluded." Choi v. Tower Rsch. Cap. LLC, 2 F.4th 10, 20 (2d Cir. 2021).

An expert's opinion must also have "a reliable basis in the knowledge and experience of his discipline." Daubert, 509 U.S. at 592. In general, Daubert laid out "non-exclusive factors that a court may consider in determining the reliability of expert testimony." United States v. Jones, 965 F.3d 149, 159 (2d Cir. 2020). They are:

> (1) whether a theory or technique has been or can be tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the technique's known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation, and (5) whether the technique is generally accepted in the relevant scientific community.

Id. (citation omitted).

This Daubert inquiry, however, is "fluid and will necessarily vary from case to case." Amorgianos v. Nat'l R.R. Passenger Corp., 303 F.3d 256, 266 (2d Cir. 2002). "Daubert is not a definitive checklist or test for the reliability of expert testimony." United States v. Ulbricht, 858 F.3d 71, 116 n.50 (2d Cir. 2017) (citation omitted). "Whether Daubert's specific factors are, or are not, reasonable measures of reliability in a particular case is a matter that the law grants the trial judge broad latitude to determine." Id. (citation omitted). Accordingly, a district court has "broad discretion in determining what method is appropriate for evaluating reliability under the circumstances of each case." Amorgianos,

303 F.3d at 265.

There is no requirement that all expert testimony express opinions or conclusions that have been "established to a degree of scientific certainty." Restivo v. Hessemann, 846 F.3d 547, 577 (2d Cir. 2017). All experts, including "economists[,] may express professional opinions that fall short of definitive proof" as long as their testimony is reliable under Rule 702. Id. at 576. Instead, a court must "assess whether the expert employs the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Id. at 577. A contention that an expert's assumptions are unfounded may "go to the weight, not the admissibility, of the testimony." Id. Because "our adversary system provides the necessary tools for challenging reliable, albeit debatable, expert testimony," "vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Amorgianos, 303 F.3d at 267 (quoting Daubert, 509 U.S. at 596).

While a "minor flaw in an expert's reasoning or a slight modification of an otherwise reliable method will not render an expert's opinion per se inadmissible," an expert's testimony should be excluded "if the flaw is large enough that the expert lacks good grounds for his or her conclusions." Id. (citation

omitted). "[N]othing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert." Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997). "[A] trial judge should exclude expert testimony if it is speculative or conjectural or based on assumptions that are so unrealistic and contradictory as to suggest bad faith." Restivo, 846 F.3d at 577 (citation omitted). When evaluating the reliability of expert testimony, "it is critical that an expert's analysis be reliable at every step." Amorgianos, 303 F.3d at 267. "[A]ny step that renders the analysis unreliable . . . renders the expert's testimony inadmissible." Id. (citation omitted).

I. The Defendants' Motion

The Defendants move to exclude Hemphill's opinions on causation, one of his standards for assessing competitive effects, and Vyera's excess profits. The motion is denied.

A. Hemphill's Causation Testimony

In his direct testimony, Hemphill opines that Vyera's agreements with distributors "impaired the opportunities" of Vyera's rivals "to a degree that made a difference to competition," and that its agreements with suppliers "raised its

rivals' costs and impeded their entry."[3] The Defendants make essentially three arguments in support of their motion to strike this testimony.

First, the Defendants contend that this testimony is at odds with Hemphill's deposition testimony, when he disclaimed that he was offering any opinion on the question of whether Vyera's alleged conduct caused anticompetitive effects. They argue that Hemphill should not be allowed to resurrect in his trial testimony an opinion he expressly abandoned during his deposition. The Defendants have not shown that these opinions should be stricken as previously abandoned such that it would be unfair to allow them to appear in the trial testimony. To the extent that the Defendants believe there is any tension between the trial testimony and the deposition testimony, they may explore the issue during cross-examination.

Second, the Defendants next argue that Hemphill lacks the expertise necessary to give this opinion. Not so. He is testifying as an economist and his opinion falls squarely within

[3] The Plaintiffs allege that Vyera's agreements with distributors restricted access to bottles of Daraprim that generic drug companies needed to conduct the bioequivalence testing mandated by the Food & Drug Administration ("FDA") before the agency would approve entry of a generic drug into the U.S. market. The Plaintiffs further allege that Vyera's agreements with suppliers restricted access to the active pharmaceutical ingredient ("API") pyrimethamine, which generic drug companies needed to manufacture a generic version of the drug.

his area of expertise.

Finally, the Defendants argue that the opinion must be rejected as unreliable. The Defendants have not shown that the opinion must be stricken under the standards that apply pursuant to Rule 702, Fed. R. Evid. Hemphill describes the events upon which he is relying in forming his opinion. Those events and this kind of opinion are features of economic analysis and it is helpful to a court to receive such testimony.

B. Hemphill's Anticompetitive Effects Framework

Hemphill opines that anticompetitive harm arises when three conditions exist. The Defendants do not object to his statement of two of these conditions: when a drug maker is able to exercise market power and charge a supracompetitive price in the absence of competition, and when the challenged conduct does not have a demonstrated procompetitive effect that offsets the harm to purchasers. The Defendants do challenge his statement of the second condition: that the exclusion is sufficiently effective as to make a difference to competition.

The Defendants first argue that the statement of the second condition must be stricken because it is unsupported by the economic literature. The parties spar in their motion practice over the extent to which this condition is or is not supported in economic theory. This issue is a proper subject for cross-examination. It is not a ground for excluding the testimony.

The Defendants next argue that Hemphill's statement of the second condition is at odds with the relevant legal standard, which the Defendants state as requiring that the challenged restraint have "a substantial anticompetitive effect that harms consumers in the relevant market." Ohio v. Am. Express Co., 138 S. Ct. 2274, 2284 (2018) (emphasis added). Defendants assert that because Hemphill cannot identify a metric to distinguish between degrees of effect on the market, he sets a standard for anticompetitive effects somewhere below "substantial."

The Defendants have used this prong of their Daubert motion to argue about the correct legal standard to be applied at trial. That is not the proper role of a Daubert motion. The parties have presented their proposed conclusions of law and their arguments about the correct standard to be applied at this trial in other documents submitted with the Pretrial Order. It is not the role of the expert to advise a court regarding the legal standard to be applied. Hemphill's opinion is given as an economist and his views regarding the anticompetitive effect of the Defendants' conduct fall squarely within that expertise and are relevant.

C. Hemphill's Calculation of Excess Profits

In the final eleven pages of his direct testimony, Hemphill calculates the excess profits associated with Vyera's exclusionary contracts with suppliers and distributors as

ranging between $52.1 and $64.6 million. He constructed a model to make his calculations under several counterfactual scenarios, using two alternate dates for the entry of the first generic competitor with Daraprim (October or December 2018), a later date for the entry of a second generic entrant, and two alternative dates when Vyera would have launched its own generic product.

The Defendants contend that the calculation should be stricken in its entirety because Hemphill is unqualified to opine on the FDA regulatory process and the speed with which the FDA would have acted. The Plaintiffs do not proffer Hemphill as an expert on FDA process. He is well qualified to make a model for the calculation of excess profits obtained through anticompetitive acts. To the extent any assumption on which Hemphill relied is unsupported by the record developed by the parties at trial, then his model will be of diminished relevance.

II. The Plaintiffs' Motion to Preclude Portions of Dr. Jena's Testimony

The Plaintiffs seek to preclude Dr. Jena from offering an opinion that Vyera did not meaningfully impede competition as untethered to any economic analysis. They also seek to preclude those opinions that rely on his analysis of insurance claims data and State drug substitution laws.

A. Dr. Jena's Opinion Regarding Impairment of Competition

In a section of his testimony labelled "Generic Manufacturers were Not Delayed or Impeded by Vyera's Distribution System Practices and Exclusive API Agreements," Dr. Jena describes the efforts of five generic drug manufacturers to bring a generic competitor to Daraprim to the market. He argues that Vyera's contracts with API suppliers and its distributors did not impede generic entry and that Hemphill's conclusion that Vyera's conduct did delay that entry was flawed.

The Plaintiffs seek to strike these sections of Dr. Jena's testimony and two related paragraphs.[4] They point out that Dr. Jena does not present any economic analysis in this section of his testimony or present an economic analysis to undermine or counter the analysis presented by Hemphill. They argue as well that Dr. Jena does not apply any economic expertise to support his recital of facts and conclusions.[5] They are correct.

The passages challenged by the Plaintiffs must be stricken as well because the critique he offers of Hemphill does not arise from his role as an expert. In these passages, Dr. Jena largely presents his own views of different paths that generic

[4] The Plaintiffs seek to strike paragraphs 41, 47, and 55-82.

[5] The Plaintiffs also point out that Dr. Jena misstates the standard for a rule of reason antitrust case and relies instead on the framework used for assessing a claim for damages in an action brought by private parties.

drug manufacturers might have taken as they attempted to enter this market and argues that it might have been "possible" for the manufacturers to launch a generic product sooner if they had made those different choices. Dr. Jena has no expertise to present opinions about generic drug manufacturers' operations or decision-making. Nor may he invade the province of the factfinder. To the extent his arguments are well founded, they may emerge at trial through the cross-examination of witnesses or in counsels' summation arguments.

B. Dr. Jena's Quantitative Analysis of Insurance Claims Data

To analyze whether patients with toxoplasmosis use only or primarily pyrimethamine, Dr. Jena analyzed insurance claims data from the OptumHealth Care Solutions Inc. Employer Claims Database ("Optum Database"). The database included 3,401 patients diagnosed with toxoplasmosis for the period between 2006 and the first quarter of 2017. The data shows the therapy used after the patient's first toxoplasmosis diagnosis. Dr. Jena observes that beginning in 2013 there is a steady downward trend in days of supply for the three most prominent treatments: Daraprim, TMP-SMX, and atovaquone. He observes as well that after Vyera's acquisition of Daraprim in August 2015, there is a "noticeable downward shift" in Daraprim usage. In fact, Dr. Jena's graphic display of data shows no use of

Daraprim from the fourth quarter of 2015 onward.

The Plaintiffs move to exclude the Optum Database discussion from Dr. Jena's testimony because the database is a small, unrepresentative sample from which reliable conclusions cannot be drawn.[6] For example, while the database shows no use of Daraprim after Vyera's August 2015 price increase, it is undisputed that almost 300,000 Daraprim tablets were sold in the twelve months following the price increase. The flaws with the database include the absence of data for hospitalized patients or those without private insurance.

This database is too unrepresentative to provide reliable support for any expert opinion or fact-finding. When the methodology followed by the expert is unreliable, the testimony must be stricken.

The Defendants argue that data from the Optum Database has been used in academic studies and elsewhere. They argue as well that the limitations in the data should go to its weight and not its admissibility. Under the standards articulated in Daubert and its progeny, however, the flaws in this database are too profound to support the use for which it is proffered in this case.

[6] The Plaintiffs move to strike paragraphs 86, 105-109, and 116.

C. Dr. Jena's Testimony about State Drug Substitution Laws

Dr. Jena observes that many States have regulations allowing pharmacists to automatically switch patients' prescriptions to generic versions of the branded pharmaceutical. He uses this and other observations to critique Hemphill's comparison of consumer purchasing behavior after March 2020, when a generic drug entered the market to compete with Daraprim.

The Plaintiffs seek to strike a few paragraphs in Dr. Jena's affidavit that refer to these State regulations on the ground that Dr. Jena is not an expert in such State laws and has an inaccurate understanding of generic substitution programs.[7] They argue as well that Dr. Jena has applied no methodology to the comparison of consumer behavior.

The motion to strike these passages is denied. The Plaintiffs' arguments largely go to the weight of Dr. Jena's testimony and can be addressed through cross-examination. Dr. Jena does not offer this testimony as an expert on State drug regulations, but as an economist offering observations about consumer behavior.

D. Dr. Jena's Testimony about Cost Structures of Branded Drug Manufacturers

Dr. Jena explains that generic drug manufacturers typically

[7] The Plaintiffs seek to strike paragraphs 125, 127-30, and 132.

face lower costs than branded drug manufacturers. The Plaintiffs move to strike two paragraphs since, whatever may be true typically, in this case Vyera made no investment to develop Daraprim.[8] Dr. Jena conceded at his deposition that these differences are not relevant in this case. The testimony is stricken pursuant to Rules 401 and 403, Fed. R. Evid.

Conclusion

The Defendants' October 20, 2021 motion to exclude the testimony of Hemphill is denied. The Plaintiffs' October 20, 2021 motion to exclude the testimony of Dr. Jena is granted in part.

Dated: New York, New York
November 12, 2021

DENISE COTE
United States District Judge

[8] The Plaintiffs move to strike paragraphs 125-26.